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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,947	01/05/2004	Mitsutoshi Tatara	159-82	2059

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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1618

DATE MAILED: 09/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/750,947	Applicant(s) TATARA ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-10 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-10 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/786,815.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>01/05/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 06/29/05. Claims 1, 4-10 and 16 are pending.

Claim Objections

1. The objection of claims 4-12 under 37 CFR 1.75(c), as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, is withdrawn because the amendment to the claims overcomes the objection.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the amendment overcomes the rejection.

3. The rejection of claims 14 and 15 under 35 U.S.C. 101 is withdrawn because claims 14 and 15 are canceled.

Response to Arguments

With respect to Friedman and Lerner, applicants argue that because claim 11 was not rejected over Friedman and Lerner, Friedman and Lerner rejections are overcome. With regard to Ganguly, applicants argue that the Ganguly art is overcome because, claim 3, which is now incorporated into claim 1, was not rejected over Ganguly, the Ganguly art is overcome.

However, while that may be the case, any new rejection(s) will be as a result of the amendment. It is also noted that all claims were previously rejected under art.

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It is also noted that future intended use is not accorded patentable weight. Intraoral topical administration is the route of administration of the composition and future intended use of the formulation and route of administration carries no patentable weight in a composition.

Claim 1 is a composition comprising a penem antibiotic, active ingredient and water-insoluble polymer. The water insoluble polymer is further defined in claim 4. The solvents are listed in claim 5.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4, 5, 7-10 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Alfonso et al. (US 4,540,579).

Alfonso discloses a dosage form in the form of lotion, cream ointment and sprays comprising penem antibiotic (abstract; column 3, lines 28-30; column 4, lines 2-4). The dosage form comprises carriers such as lactose, sorbitol for the sugars, ethyl cellulose for the cellulose and derivatives, dicalcium or tricalcium phosphate, vegetable oils, surfactants, ethylene glycol polymers and non-toxic compatible fillers, binders, disintegrants and lubricants; preservatives may optionally be included (column 4, lines 5-28). Ethyl cellulose is a water insoluble polymer; calcium phosphate is a pH adjuster; ethylene glycol polymer is a solvent. Future intended use is not accorded patentable weight. Intraoral topical administration is the route of administration of the composition and future intended use of the formulation and the route of administration carries no patentable weight in a composition claim. Alfonso meets the claims.

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6. Claims 1, 4-10 and 16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ganguly et al. (US 4,743,598).

Ganguly discloses compositions that contain penem antibiotics, solvent, polymer, oils fillers, binders, disintegrants, buffering agents and the composition is formulated as lotion, creams and ointments (abstract; column 1, line 16 to column 3, line 61., column 3, lines 29-31). Although future intended use is not accorded patentable weight in composition claims, it is noted that the composition of Ganguly is administered topically. Intraoral topical administration is the route of administration of the composition and future intended use of the formulation and route of administration carries no patentable weight in a composition claims. Ganguly meets the limitations of the claims.

7. The rejection of claims 1, 4-10 and 16 under 35 U.S.C. 102(e) as being anticipated by Lerner et al. (US 6,197,331) is withdrawn because amended claim has penem antibiotic as the active agent and Lerner's active agent is not penem antibiotic.

8. The rejection of claims 1, 4-10 and 16 under 35 U.S.C. 102(b) as being anticipated by Friedman et al. (US 5,648,399) is withdrawn because Friedman does not disclose the penem antibiotic that is not recited in amended claim 1.

Claim Rejections - 35 USC § 103

9. Claims 1, 7-10 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuta et al. (US 6,187,340) in view of Ganguly et al. (US 4,743,598) or in view of Christensen et al. (US 4,388,310).

Fukuta discloses penem antibiotic containing formulation (abstract; column 8, line 49); the formulation comprises antioxidants (column 2, lines 21, 22, 29-31 and 42), polyethylene glycol (column 2, line 26); triethyl citrate or dibutyl phthalate or triacetin (column 4, lines 37 and 38);

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propylene glycol or polyethylene glycol (column 4, line 41); enteric polymers or water insoluble polymer such as EUDRAGIT L, shellac, HPMCP (column 5, lines 58-67); and the formulation is sustained release (column 6, line 1) in the form of tablets or powders or granules or pills (column 14, lines 60-67).

Fukuta differs from the claimed invention by formulating the formulation in solid dosage form. However, it is known in the art to formulate penem antibiotics as ointments or creams or lotions. For example, Ganguly formulates penem as ointment or cream or lotion as disclosed above under 35 USC 102. Christenson formulates penem antibiotics for topical administration in the form of ointments, creams, lotions, paints or powders (column 8, lines 29-37; column 9, lines 27-29) in the presence of polyethylene glycol (12, lines 14-16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the formulation of Fukuta. One having ordinary skill in the art would have been motivated to formulation of Fukuta as an ointment or lotion or cream with the expectation of administering it topically. Thus Ganguly and Christensen are relied upon in this rejection for formulating penem antibiotic as ointment or lotion or cream.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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